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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/783,628 | 02/20/2004 | Ricardo E. Paxson | MWS-108 | 7206 |

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| EXAMINER | |
|---|---|
| ZHOU, SHUBO | |
| **ART UNIT** | **PAPER NUMBER** |
| 1631 | |
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| 10/30/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/783,628 | PAXSON ET AL. | |
| | Examiner | Art Unit | |
| | Shubo (Joe) Zhou | 1631 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *13 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-87* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-12, 15-18, 20, 22, 26-30, 33-37, 40-43, 45, 47, 52-67 and 77-87* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 August 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 1-7,13,14,19,21,23-25,31,32,38,39,44,46,48-51 and 68-76.

## DETAILED ACTION

Applicant's amendments and request for reconsideration filed 8/13/07 are acknowledged and the amendments are entered. The terminal disclaimer filed 8/13/07 is also acknowledged and approved.

Applicant's arguments in response to the previous Office action mailed 3/12/07 have been fully considered but they are not deemed to be completely persuasive. The following rejections and/or objections are either reiterated from the previous Office action or newly applied but necessitated by applicant's amendments, and constitute the complete set presently being applied to the instant application. Rejections and/or objections set forth not reiterated from the previous Office action are hereby withdrawn.

This application contains claims 1-7, 13-14, 19, 21, 23-25, 31-32, 38-39, 44, 46, 48-51, and 68-76 drawn to an invention nonelected with traverse in the communication filed 12/6/06. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 8-12, 15-18, 20, 22, 26-30, 33-37, 40-43, 45, 47, 52-67 and 77-87 are currently under consideration.

### *Claim Rejections-35 USC § 101*

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 20-22, 26-30, 45, 47, and 64-67 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

This rejection is reiterated from the previous Office action.

The claims are drawn to a process of integrated modeling and simulation of a biological process comprising constructing a model of the biological process in a modeling component, analyzing the constructed model to generate a result and transmitting the result to the modeling component.

The following analysis of facts of this particular patent application follows the rationale suggested in the "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (OG Notices: 22 November 2005, available from the US PTO website at http://www.uspto.gov/web/offices/com/sol/og/2005/week47/og200547.htm).

The Guidelines states:

> *To satisfy section 101 requirements, the claim must be for a practical application of the § 101 judicial exception, which can be identified in various ways (Guidelines, p. 19):*
>
> *- The claimed invention "transforms" an article or physical object to a different state or thing.*
> *- The claimed invention otherwise produces a useful, concrete and tangible result, based on the factors discussed below.*

In the instant case, at least one embodiment of the claimed invention merely manipulates data and performs a series of calculations by mathematical functions for constructing a model and analyzing the model. Thus, the process does not appear to transform an article or physical object to a different state or thing outside a computation device.

Furthermore, the invention does not produce a useful, concrete and tangible result. Specifically it does not produce a tangible result. Since the process merely manipulates data and performs a series of calculations entirely within the confine of a computing device without using

or making available for use the results of the manipulation to enable its functionality and usefulness to be realized.

Applicant's arguments filed 8/13/07 have been fully considered but they are not persuasive. Applicant argues that the amended claims filed 8/13/07 now have the limitation that the result is saved in a storage element thus generating a tangible result. This is not found persuasive because the result stored would not be necessarily be accessible to a user. Outputting our displaying such result to a user may overcome the rejection. Furthermore, step (b) of claim 20, etc. only generate an intangible "result" but not clear what the result is.

***Claim Rejections-35 USC § 112***

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-12, 15-18, 20, 22, 26-30, 33-37, 40-43, 45, 47, 52-67, and 77-87 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 15-18, 40-43 and 77-78 recite various means-plus-function limitations including "means for constructing a model of a biological process," "means for generating ... an expected output of the modeled biological process," and "means for displaying the dynamic behavior," as recited in claim 15, etc. These "means-plus-function" recitations invoke 35 USC 112, sixth paragraph, which states that a claim limitation expressed in means-plus-function language "shall

be construed to cover the corresponding structure...described in the specification and equivalents thereof." "If one employs means plus function language in a claim, one must set forth in the specification an adequate disclosure showing what is meant by that language." In the instant case, the specification fails to set forth an adequate disclosure showing what is meant by "means for constructing a model of a biological process," "means for generating ... an expected output of the modeled biological process," and "means for displaying the dynamic behavior." Thus, one skilled in the art would reasonably doubt that the inventor, at the time the application was filed, had possession of the claimed invention.

Applicant argues that these means plus functions are defined adequately in the specification. For example, applicant argues that Figure 1 and page 15, line 25 through page 16, line 17, provide support for the "computer-readable program means for constructing a model of a biological process, wherein said model is constructed or modified by instructions received through both a graphical user interface and a textual interface" as recited in claim 15. This is not found persuasive because Figure 1 and page 15, line 25 through page 16, line 17 only provide a generic computer environment for modeling, but no support for the specifically recited "computer-readable program means for constructing a model of a biological process, wherein said model is constructed or modified by instructions received through both a graphical user interface and a textual interface." Similarly, Figure 1 does not provide adequate support for the specifically recited "computer-readable program means for generating, using the constructed model of the biological process, an expected output of the modeled biological process."

It should be pointed out that these various means-plus-function limitations are specific means for specific functions. 35 USC 112, sixth paragraph, requires that a claim limitation

expressed in means-plus-function language "shall be construed to cover the corresponding structure...described in the specification and equivalents thereof." If one employs means plus function language in a claim, one must set forth in the specification an adequate disclosure showing what is meant by that language. In the instance, all the means-plus-functions represent specific structures of the claimed article, but the supports applicant pointed out, such as for claim 15 discussed above, are only generic structures, and the specification at those sections and Figures does not describe that those generic structures can perform the specific functions in the instant claims such as those in claim 15 above.

In the amendment filed 8/13/07, independent claims 8, 15, 20, 26, 33, 40 and 45, as well as their dependent claims, are amended to recite the limitation that a model "is constructed or modified by instructions received through both a graphical user interface and a textual interface." Applicant did not specifically point out, and the Office could not find, specific support for this limitation in the specification, especially the features of the model being "modified by instructions," and "instructions received through both a graphical user interface and a textual interface."

The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-12, 15-18, 20, 22, 26-30, 33-37, 40-43, 45, 47, 52-67, and 77-87 are rejected under 35 U.S.C. 112 , second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 8, 15, 20, 26, 33, 40 and 45, as well as their dependent claims, are amended to recite the limitation that a model "is constructed or modified by instructions received through both a graphical user interface and a textual interface." The metes and bounds of the claimed invention are not clear because firstly it is unclear as to what is meant by the model being "modified," i.e. unclear whether it means the modeling is constructed by modifying an existing model or it actually means that the model is constructed de novo but with modifications during the process. Secondly, it is unclear whether the "instructions" must be computer executable instructions, i.e. computer programs, or can be any instructions. Thirdly, absent a clear definition for the terms in the specification, it is unclear whether the graphical interface and textual interface are mutually exclusive or one can also be the other.

Furthermore, as set forth in the previous Office action and reiterated above, claims 15-18, 40-43 and 77-78 recite "means-plus-function" limitations, thus invoking 35 USC 112, sixth paragraph.

The MPEP 2181(II) states:

> *If an applicant fails to set forth an adequate disclosure, the applicant has in effect failed to particularly point out and distinctly claim the invention as required by the second paragraph of section 112." In re Donaldson Co., 16 F.3d 1189, 1195, 29 USPQ2d 1845, 1850 (Fed. Cir. 1994) (in banc).*

In the instant case, the specification does not provide an adequate disclosure showing the structure, material or acts for these "means-plus-function" limitations, for reasons as set forth above. Thus, one skilled in the art would not know what are meant by these "means-plus-function" limitations, and the metes and bounds of the claimed invention are thus unclear.

Applicant's arguments regarding support for the means-plus-function limitations are not persuasive for the same reasons set forth above for the written description rejection under 35 USC 112, first paragraph set forth above.

Clarification of the metes and bounds of the claims is requested.

***Claim Rejections-35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-12, 15-18, 20, 22, 26-30, 33-37, 40-43, 45, 47, 52-67 and 77-87 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kelly et al. (IDS document: WO 03/001891, 09 January 2003).

The claims are drawn to a method and system for modeling and simulation of a biological process comprising constructing a model of a biological process, generating using the model dynamic behavior of the modeled biological process, and displaying the dynamic behavior on a display device.

Kelly et al. disclose a method and system for modeling and simulation of immune system including various biological processes. The method comprises providing data using graphical user interface and constructing a model of the immune system comprising components of immune responses using various mathematical equations including stochastic differential equations and Effect Diagram (see at least pages 9, 15), validating the model and using the model to produce simulated biological attributes associated with the biological state of the immune responses and compare simulated biological attributes with a corresponding biological attribute of a reference pattern of the immune response, which simulated biological attributes are interpreted as being dynamic behavior of the modeled process. See at least Fig. 3 and pages 43-44. These are displayed in the various drawings disclosed by Kelly et al. Furthermore, as the

modeling, simulation and validation are also performed in computer systems with monitors and other display devices, all the results would be inherently displayed in the display devices involved. The Effect Diagram used in the modeling is considered a block diagram. Kelly et al. also disclosed the computer system and computer programs including codes for executing the method of modeling and simulations. See at least pages 41-42.

Applicant's arguments filed 8/13/07 have been fully considered but they are not found persuasive. Applicant argues that Kelly et al. do not teach the newly added limitation that the model is constructed or modified by instructions received through both a graphical user interface and a textual interface." This is not found persuasive. Firstly, Kelly et al. state on page 11 that their "model can be modified to reflect .... The regions of interface can, for example, include ...." This indicates that their model can be identified and interface is used. Secondly, Kelly et al. disclose that the computer system used for their modeling comprises a video display on which a user interface is displayed, which is interpreted as a graphical interface, and a network interface, which is interpreted as a textual interface, given the indefiniteness for the terms graphical interface and textual interface and the entire limitation set forth above in the rejection under 35 USC 112, second paragraph above. Considering Kelly et al. disclose that their model can be executed by computer-executable software code representing dynamic biological processes including adaptive immune response (see page 8), it would be readily apparent to one skilled in the art that the model can be constructed or modified by receiving computer executable instructions received through the graphical and textual interfaces.

***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. §1.136 (a). A shortened statutory period for response to this final action is set to expire three months from the date of this action. In the event a first response is filed within two months of the mailing date of this final action and the advisory action is not mailed until after the end of the three-month shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136 (a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than six months from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of

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/Shubo (Joe) Zhou/

Shubo (Joe) Zhou, PH.D.

Primary Examiner